

## REMARKS

Entry of the foregoing, reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. §1.112, are respectfully requested in light of the remarks which follow.

Claims 25-48 are pending in the application and Claims 25-45 and 47-48 are withdrawn from consideration. Claim 46 has been amended herein. No new matter is submitted herewith. Applicants reserve the right to file at least one continuation application directed to any subject matter canceled by way of the present Amendment.

### **Specification Objections**

The Office notes the use of the trademarks Apozepam, Mebumal Vet, Hypnodil, Ketalar, Stersnil, Humicade, Roquininex, Ariflo, Orthegen, Orthokin in the specification and requires that they be capitalized and be accompanied by the generic terminology, as needed. The specification is amended in this regard. Thus, this objection is obviated.

### **Claim Objections**

Claim 46 is objected to as depending from a non-elected claim. Claim 46 has been amended to include all the limitations of claim 25, the non-elected claim from which it depends, as requested by the Office. Therefore, this objection is obviated.

### **Claim Rejection Under 35 U.S.C. § 112**

Claim 46 is rejected under 35 USC § 112, first paragraph, as purportedly failing to comply with the written description requirement. Applicant respectfully traverses.

The Office alleges that claim 46 and the specification fail to adequately describe peptide derivatives of lactoferrin. The Office states that "[t]he claim does not require that the polypeptide possess any particular conserved structure, or other distinguishing feature, such as a specific biological activity." However, claim 46 recites a specific biological activity, namely inhibition of a pro-inflammatory cytokine. In addition, the specification provides peptides disclosed in WO 00/01730 as

examples of peptides derived or derivable from lactoferrin (see page 10, lines 5-7). By this reference, the specification identifies a particular portion of the lactoferrin molecule characteristic of the claimed genus. Thus, a person of ordinary skill in the art can envision the detailed chemical structure of the encompassed genus of polypeptides.

In light of the above, Applicant requests that the rejection under 35 U.S.C. § 112 be withdrawn.

### **Claim Rejections Under 35 U.S.C. § 102**

Claim 46 is rejected under 35 USC § 102(e) as purportedly being anticipated by Reuben et al. (U.S. Publication No. 2002/0072596). This rejection is respectfully traversed.

To anticipate a claimed invention under 35 U.S.C. §102, a reference must teach each and every element of the claimed invention. See, e.g, *Lindeman Machinenfabrik GmbH v. American Hoist and Derrick Company*, 221 USPQ 481, 485 (Fed. Cir. 1984). Applicant submits that Ruben et al. does not teach each and every element of the present invention.

Ruben et al. discloses transferrin sequences, two of which (SEQ ID NO: 4 and SEQ ID NO: 6) can be derived from the lactoferrin molecule. Furthermore, sections [0590] and [0591] of Ruben et al. disclose methods for treating hypertrophic scars and keloids. However, the disclosed methods are said to comprise the step of administering "a polynucleotide, polypeptide, antagonist and/or agonist of the invention." Ruben et al. makes a clear distinction between "polypeptide" and "polypeptide fragment," see e.g. claim 11 and sections [0035], [0037], [0038], [0042], [0082], [0092], [0093], and [0115]. Sections [0590] and [0591] speak of "polypeptides" only, not "polypeptide fragments." Thus, Rueben et al. does not teach or suggest a method of using polypeptide fragments for treating hypertrophic scars and keloids.

In contrast, present claim 46 recites "peptides derived from lactoferrin." According to the present application as filed, "peptides derived from lactoferrin" are polypeptide fragments exemplified as those peptides disclosed in WO 00/01730, i.e. peptides derived from amino acid 12 to amino acid 40 of human lactoferrin.

Applicants submit that the "peptides derived from lactoferrin" of the present application are different from the "polypeptides" contemplated to be used in the methods disclosed in sections [0590] and [0591] of Ruben et al.

Thus, the present claim is novel over Reuben et al., and Applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 46 is also rejected under 35 USC § 102(b) as purportedly being anticipated by Mita et al. (U.S. Patent No. 5,561,109). This rejection is respectfully traversed.

Applicant submits that Ruben et al. does not teach each and every element of the present invention.

Mita et al. discloses a method for the healing of wounds caused by corneal injury in a mammalian patient, which comprises administering to the mammalian patient an effective corneal wound healing amount of an active ingredient consisting essentially of lactoferrin (see claim 5). However, Mita et al. does not disclose or suggest the use of lactoferrin derived peptides.

In contrast, present claim 46 is directed to a method for treating a wound and/or improving wound healing wherein a therapeutically effective amount of a pharmaceutical composition comprising a peptide derived or derivable from lactoferrin is administered to a patient. Applicants submit that the "peptides derived from lactoferrin" of the present application are different from the full-length lactoferrin disclosed in Mita et al.

Thus, the present claim is novel over Mita et al., and Applicants respectfully request reconsideration and withdrawal of this rejection.

#### **Double Patenting Rejection**

Claim 46 is provisionally rejected on the ground of non-statutory obviousness-type double patenting as allegedly being unpatentable over claims 1 and 23 of copending application No. 10/092,919.

This rejection is a *provisional* rejection only, because the allegedly conflicting claims have not yet been allowed. Applicants will consider filing a Terminal Disclaimer, if appropriate, once allowable subject matter is determined.

**CONCLUSION**

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this Amendment and Reply, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney at 703-838-6563 concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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